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Certifier A. Corbin

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0352]

Global Harmonization Task Force, Study Groups 1 and 2; New Proposed Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two proposed documents that have been prepared by Study Groups 1 and 2 of the Global Harmonization Task Force (GHTF). These documents are intended to provide information only and represent a harmonized proposal and recommendation from the GHTF Study Groups that may be used by governments developing and updating their regulatory requirements for medical devices. These documents are intended to provide information only and do not describe current regulatory requirements; elements of these documents may not be consistent with current U.S. regulatory requirements. FDA is requesting comments on these documents.

DATES: Submit written or electronic comments on any of the documents by [*insert date 90 days after date of publication in the* **Federal Register**]. After the close of the comment period, written comments may be submitted at any time to the contact persons listed in this document.

ADDRESSES: Submit written comments on the documents to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http:/*

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/www.fda.gov/dockets/ecomments. Comments should be identified with the docket number found in brackets in the heading of this document. If you do not have access to the Internet, submit written requests for single copies on a 3.5″ diskette of the document to the Division of Small Manufacturers, International and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. See the **ELECTRONIC ACCESS** section for information on electronic access to these documents.

FOR FURTHER INFORMATION CONTACT:

For Study Group 1: Ginette Michaud, GHTF, Study Group 1, Office of In Vitro Diagnostic Devices (HFZ–440), Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293, ext. 157;

For Study Group 2: Stephen Sykes, GHTF, Study Group 2, Office of Surveillance and Biometrics (HFZ–500), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3673.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements. In September 1992, a meeting was held in Nice, France by senior regulatory officials to evaluate international harmonization. At this time it was decided to form a GHTF to facilitate

harmonization. Subsequent meetings have been held on a yearly basis in various locations throughout the world.

The objective of the GHTF is to encourage convergence at the global level of regulatory systems of medical devices in order to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means considered most suitable. One of the ways this objective is achieved is by identifying and developing areas of international cooperation in order to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices. In an effort to accomplish these objectives, the GHTF has formed four study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice is a result of documents that have been developed by two of the Study Groups (1 and 2).

Study Group 1 was initially tasked with the responsibility of identifying differences between various regulatory systems. In 1995, the group was asked to propose areas of potential harmonization for premarket device regulations and possible guidance that could help lead to harmonization. As a result of their efforts, this group has developed SG1(PD)/N043R6. The purpose of SG1(PD)/N043R6 (proposed document) "Labelling (sic) for Medical Devices (revised)" is to describe harmonized requirements for the labeling of medical devices. It applies to all products that fall within the definition of a medical device that appears within the GHTF document SG1/N029 "Information Document Concerning the Definition of the Term 'Medical Device,' " including those products used for the in vitro examination of specimens derived from the human body. This document is a revised version of previously published guidance on the subject. The new version includes, in addition to the original

medical device labeling guidance, guidance on requirements for labeling of in vitro diagnostic medical devices. The new guidance is intended to supersede the previous version of the guidance.

Study Group 2 was initially tasked with the responsibility of developing guidance documents that will be used for the exchange of adverse event reports. As a result of their efforts, this group has developed SG2(PD)/N38R14. SG2(PD)/N38R14 (proposed document) "Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program" that provides information to authorized representatives on prerequisites and commitments required from an organization before they can participate in the National Competent Authority Report exchange program founded by GHTF SG2.

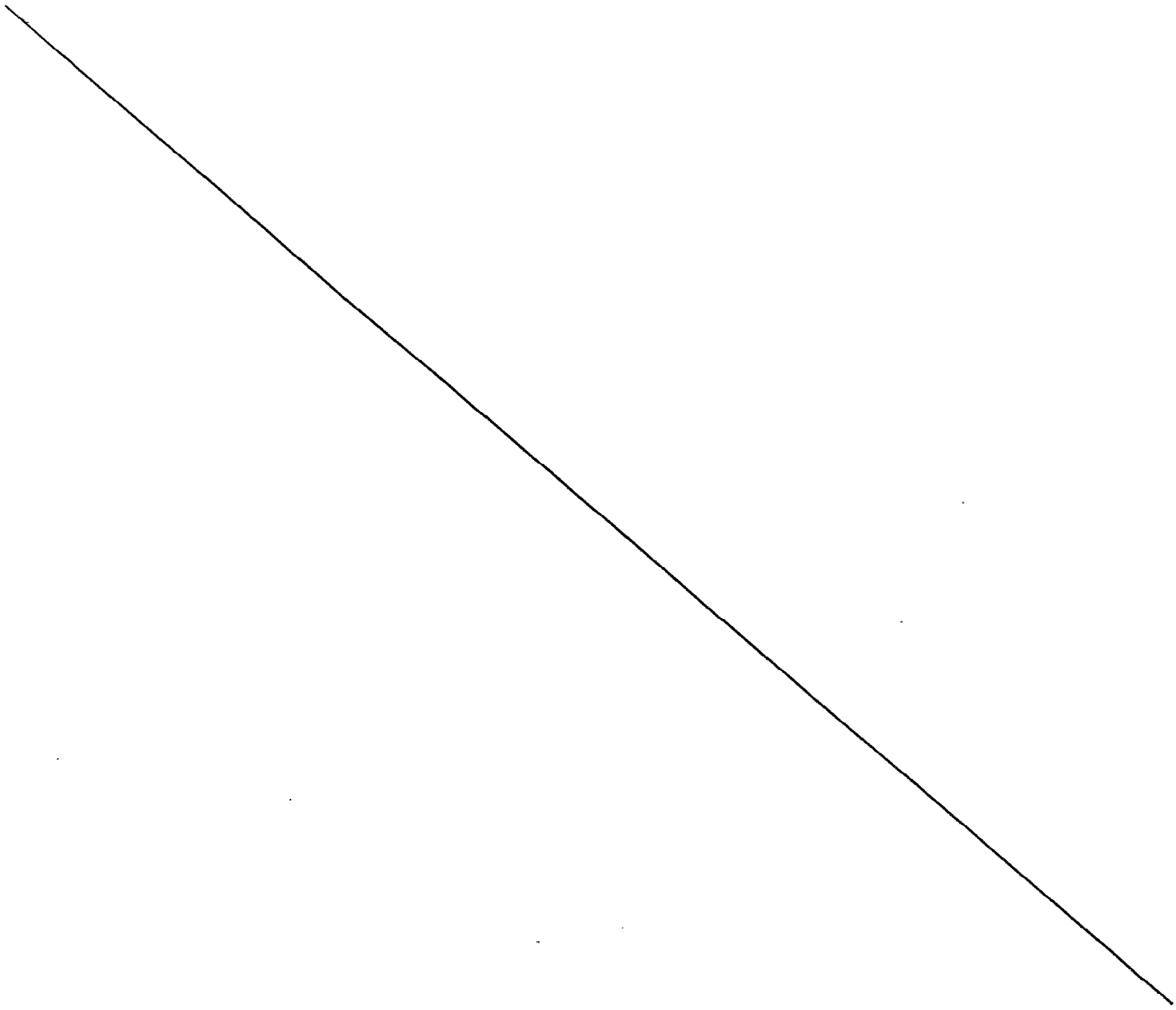
These documents represent recommendations from the GHTF Study Groups and do not describe regulatory requirements. FDA is making these documents available so that industry and other members of the public may express their views and opinions.

II. Electronic Access

Persons interested in obtaining copies of these draft documents may also do so using the Internet. Updated on a regular basis, the CDRH home page includes device safety alerts, lists of approved applications and manufacturers' addresses, small manufacturers' assistance, information on video-oriented conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at *http://www.fda.gov/cdrh*. Information on the GHTF may be accessed at *http://www.ghtf.org*.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding any of these documents. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and with the full title of these documents. The draft documents and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



Dated: 8/13/04

August 13, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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